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K013199 p.1/2

9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Quality Program Manager
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085

Tel: 978 659 3178
Fax: 978 685 5624
Email: dosborn@hsgmed.com

This summary was prepared on 21 September, 2001

2. The name of this device is the Philips Medical Systems, M1275B Component Compact Monitor. Classification names are as follows:

Device Panel	Classification	ProCode	Description
Panel 73 Anesthesiology	868.1400, II	CCK	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
	868.2375, II	BZQ	Monitor, Breathing Frequency
	868.2480, II	LKD	Monitor, Carbon-Dioxide, Cutaneous
	868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
Panel 74 Cardiovascular	870.1025, III	DSI	Detector and Alarm, Arrhythmia
	870.1025, III	MLD	Monitor, ST Segment with Alarm
	870.1025, III	MHX	Monitor, Physiological, Patient (with arrhythmia Detection or alarms)
	870.1100, II	DSJ	Alarm, Blood-Pressure
	870.1110, II	DSK	Computer, Blood-Pressure
	870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	870.1915, II	KRB	Probe, Thermodilution
	870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	870.2340, II	DPS	Electrocardiograph
	870.2340, II	MLC	Monitor, ST Segment
	870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	870.2450, II	DXJ	Display, Cathode-Ray Tube, Medical
	870.2600, I	DRJ	System, Signal Isolation

Device Panel	Classification	Procode	Description
	870.2700, II	DQA	Oximeter
	870.2770, II	DSB	Plethysmograph, Impedance
	870.2800, II	DSH	Recorder, Magnetic Tape, Medical
	870.2810, I	DSF	Recorder, Paper Chart
	-	MSX	System,Network and Communication, Physiological Monitors
Panel 80 General Hospital	880.2910, II	FLL	Thermometer, electronic, clinical

3. The new device is substantially equivalent to the previously cleared M3/M4 (M3046/3000A) device marketed pursuant to K971910, K981576 , and K990972, K991773, K992273, K993383, K000822, K001057, K001333, and K003621, as well as M1175/76A pursuant to K882609, K900032, K922058, K923682, K925910, K941811, K990125, K990476, K992595, K001722.

4. The modification is a new display unit and a modified rack.

5. The new device has the same Indications for Use, for use by health care professionals whenever there is a need for monitoring the physiological parameters patients, as the legally marketed predicate device.

6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that Component Compact Monitor meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2001

Mr. Dave Osborn
Phillips Medical Systems, Inc.
Cardiac and Monitoring Systems
3000 Minuteman Rd.
Andover, MA 01810-1099

Re: K013199
Trade Name: M1275B Component Compact Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: November 12, 2001
Received: November 13, 2001

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

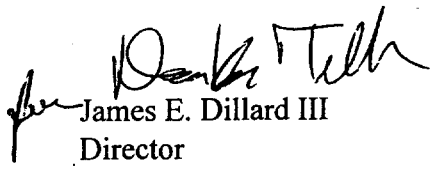
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013199

510(k) Number (if known): K013199

Device Name: Philips Medical Systems, M1275B Component Compact Monitor, Release A.01.

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters patients.

Intended use: For monitoring, recording, and alarming of multiple physiological parameters of adults, pediatrics, and neonates in health care facilities.

EASI 12-lead ECG is only for use on adult and pediatric patients.

ST Segment monitoring is restricted to adult patients only.

The transcutaneous gas measurement (tcpO2 / tcpCO2) is restricted to neonatal patients only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use**
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013199